REMARKS

Claim status

Claims 11-21 and are currently pending. Claims 11-18 have been withdrawn. By this amendment, claims 19 and 20 have been amended. No claims have been added or canceled. Upon entry of this amendment, claims 19-21 will be under examination.

Claim Rejection Under 35 U.S.C.§112-Enablement

In the Office Action, claims 19-21 stand rejected for lacking enablement. According to the Examiner, while the specification is enabled for directly delivering the recombinant adenoviral vector containing the P972 gene to tumor cells which lack P972 expression, the specification is not enabling for tumor cells which express P972 (see page 6 of the Office Action). The Examiner contends that claims 19 and 20, in their present form, encompass tumors that express P972 and tumors that lack P972.[1]

Applicant's agent confirmed the nature of this rejection in a telephone call with the Examiner on August 25, 2005. During the telephone interview, the Examiner indicated that amending claims 19 and 20 to recite that the vector is administered to cancer cells which lack P972 expression would overcome this rejection.

By this amendment claims 19 and 20 have been amended to recite that the cancer cells do not express the P972 protein.

This amendment is supported by the specification at page 9, lines 18-21, which indicates that the cells do not express the P927 protein.

[1] P972 is also referred to in the literature as GADD45gamma; OIG37; CR6; or GRP17.

In addition, the Examiner also has the opinion that the term "P972 gene" recited in claims 19 and 21 is overly-broad, since the definition provided in the specification indicates that the P972 gene includes functional equivalents in addition to the wild-type gene. According to the examiner, identification of functional equivalents would require undue experimentation by a skilled artisan.

It appears that the Examiner is requiring that the claims be limited to the specific gene used in the experiments and disclosed in deposited vector AdP972. The Examiner also contends that the reference to the GenBank Accession number is not sufficient to provide enablement for even that sequence, since the Accession number can be changed over time. To support his contention, the Examiner cites a second GenBank Accession number which he contends refers to a distinct P972 gene (No. AY689136).

For the record, it is noted that the alternate GenBank Accession number cited by the Examiner does not purport to be a P972 gene. By contrast, the sequence disclosed under that Accession number is a partial ribosomal RNA sequence from a strain of parasitic **fungus** (that causes tree disease). According to the GenBank entry, the strain of fungus is designated "P972" **and not** the depicted RNA sequence. It is submitted that one of ordinary skill in the art certainly (hopefully) would not mistake a ribosomal RNA sequence from a tree fungus with a cell-cycle control gene designated P972.

However, to address this rejection and expedite prosecution, claims 19 and 21 have been amended to recite that the P972 gene is the "wild-type" P972 gene. This is supported by the specification at page 5, lines 16-21; page 7, lines 12-15; and Example 1, page 12, lines 2-3.

In view of the foregoing, withdrawal of this rejection is respectfully requested.

Deposit Requirement

Regarding claim 20, the Examiner is of the opinion that deposition of the AdP972 vector in the Korean Collection for Type Cultures (KCTC) does not meet the requirements under the Budapest Treaty and is not considered a proper deposit.

In response, the Examiner's attention is directed to the **deposit receipt** (attached at Exhibit 1) reflecting deposit of the AdP972 in the KCTC on June 27, 2000 (prior to the filing date which complies with 37 C.F.R. 1.804(a) and MPEP 2406). The deposit receipt was filed with the application. The Examiner is reminded that the KCTC is an accepted International Depository Authority established under the Budapest Treaty according to the Manual of Patent Examination and Procedure, section 2405 (see Exhibit 2). Moreover, the deposit receipt indicates the address of the KCTC and the accession number given by the KCTC. This information also is specifically referenced in the specification at page 8, lines 5-9, therefore meeting the requirements of 37 C.F.R. 1.804(a) and MPEP 2406.01.

Further, Applicants' state that the deposited adenovirus of the instant invention will be irrevocably and without restriction released to the public upon issuance of a patent from this application.

In view of the deposit, the specification, and the above statement, it is respectfully asserted that the deposit meets the requirements of the Budapest treaty.

In view of the above amendment and remarks, it is believed that the pending application is in condition for allowance.

Dated: January 4, 2006

Respectfully submitted,

By _____

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSE OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1

TO : KIM, Daegun
Samyang Genex Biotechnology Research Institute,
#63-2, Hwaam-dong, Yusong-ku, Taejon 305-348,
Republic of Korea

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: **Ad P972 (Adenovirus)**	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: **KCTC 0806BP**

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:
[x] a scientific description
[ ] a proposed taxonomic designation
(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received by it on **June 21 2000.**

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depositary Authority on and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Korean Collection for Type Cultures Address: Korea Research Institute of Bioscience and Biotechnology (KRIBB) #52, Oun-dong, Yusong-ku, Taejon 305-333, Republic of Korea	Signature(s) of person(s) having the power to represent the International Depositary Authority of authorized official(s): BAE, Kyung Sook, Director Date: **June 27 2000**

CLAIM

1. An expression vector capable of expressing P972 comprising P972 gene and a promoter operably linked to the same to express the P972 gene.

2. The expression vector according to Claim 1, wherein the said expression vector is for the treatment of cancer.

3. The expression vector according to Claim 2, wherein the said cancer is breast cancer, cervical cancer or colon cancer.

4. The expression vector according to Claim 1, wherein the said vector is derived from adenovirus.

5. A recombinant adenovirus containing an expression vector capable of expressing P972 comprising P972 gene and a promoter operably linked to the same to express the P972 gene.

6. A cell line transformed with an adenovirus vector of claim 5.

7. A cell line transformed with an expression vector capable of expressing P972 comprising P972 gene and a promoter operably linked to the same to express

the P972 gene.

8. The cell line according to Claim 7, wherein the said expression vector is for the treatment of cancer.

9. The cell line according to Claim 8, wherein the said cancer is breast cancer, cervical cancer or colon cancer.

10. The cell line according to Claim 7, wherein the said expression vector is an adenovirus vector.

FIG. 1

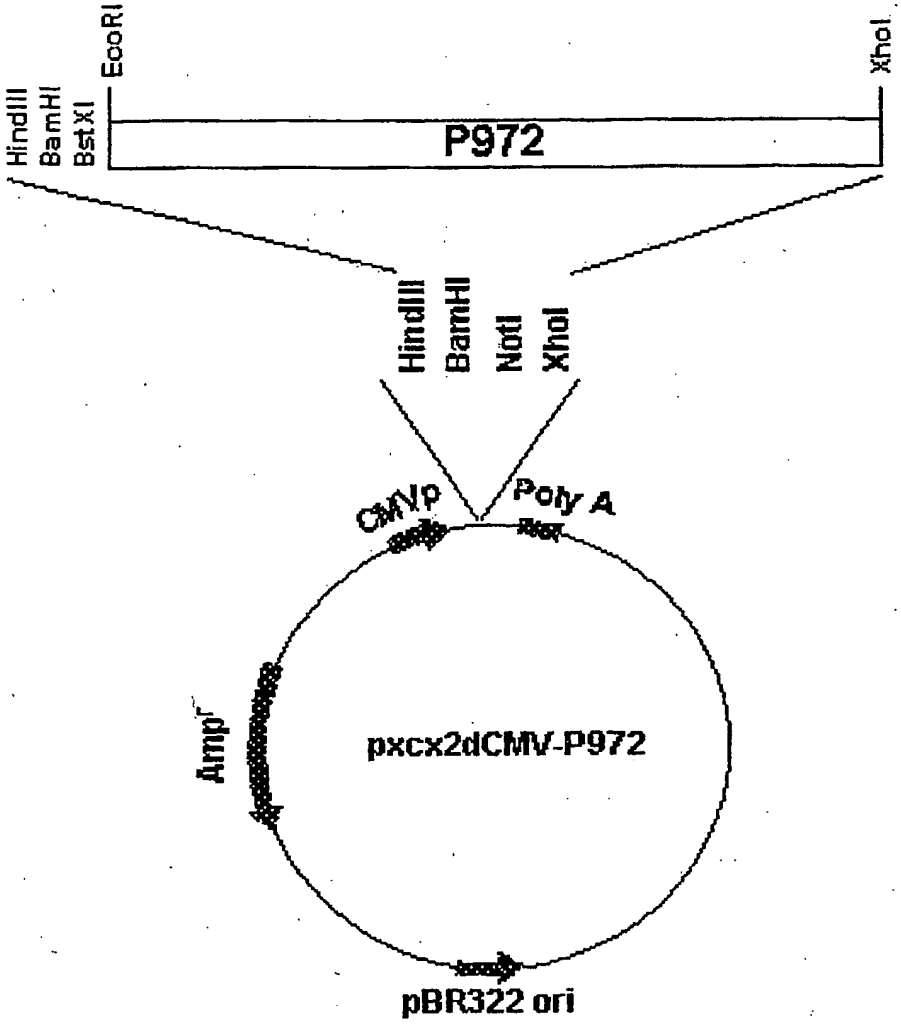

EcoRI
HindIII
BamHI
BstXI
XhoI
P972
HindIII
BamHI
NotI
XhoI
CMVp
Poly A
Amp
pxcx2dCMV-P972
pBR322 ori

FIG. 2

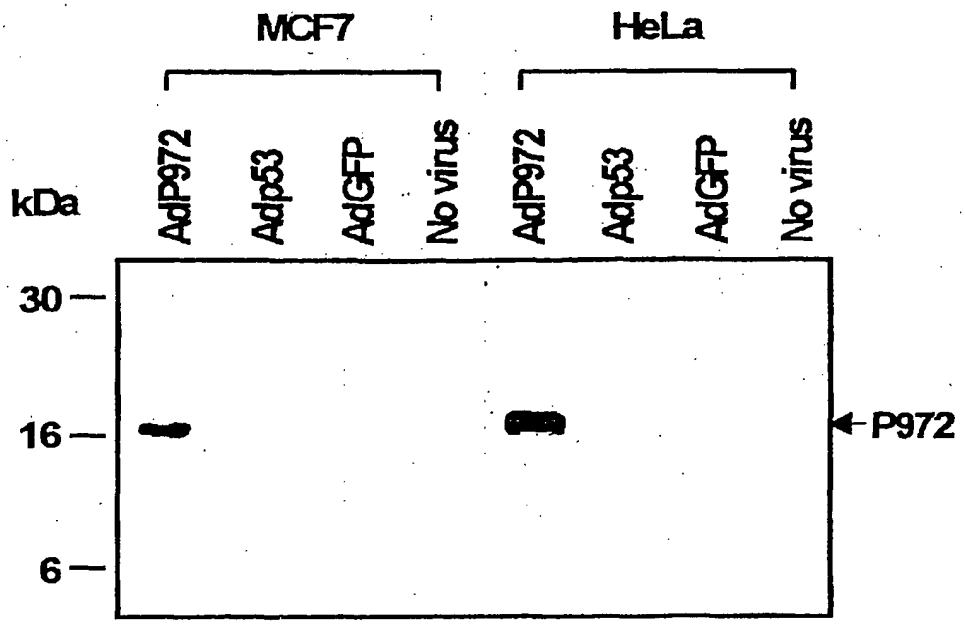

MCF7
HeLa
kDa
AdP972
Adp53
AdGFP
No virus
AdP972
Adp53
AdGFP
No virus
30
16
6
P972

FIG. 3

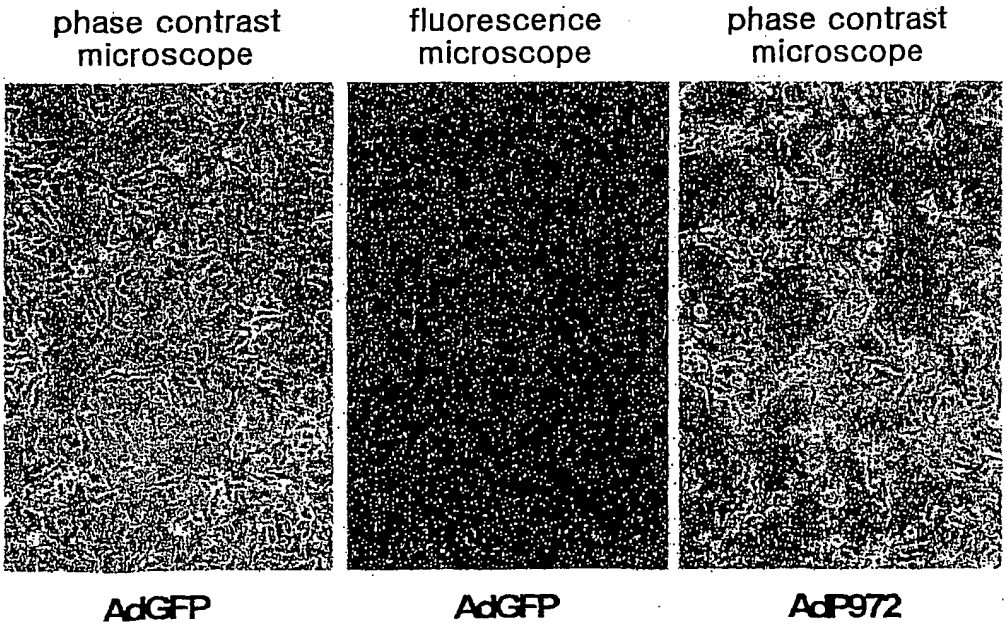

phase contrast microscope
fluorescence microscope
phase contrast microscope
AdGFP
AdGFP
AdP972

FIG. 4

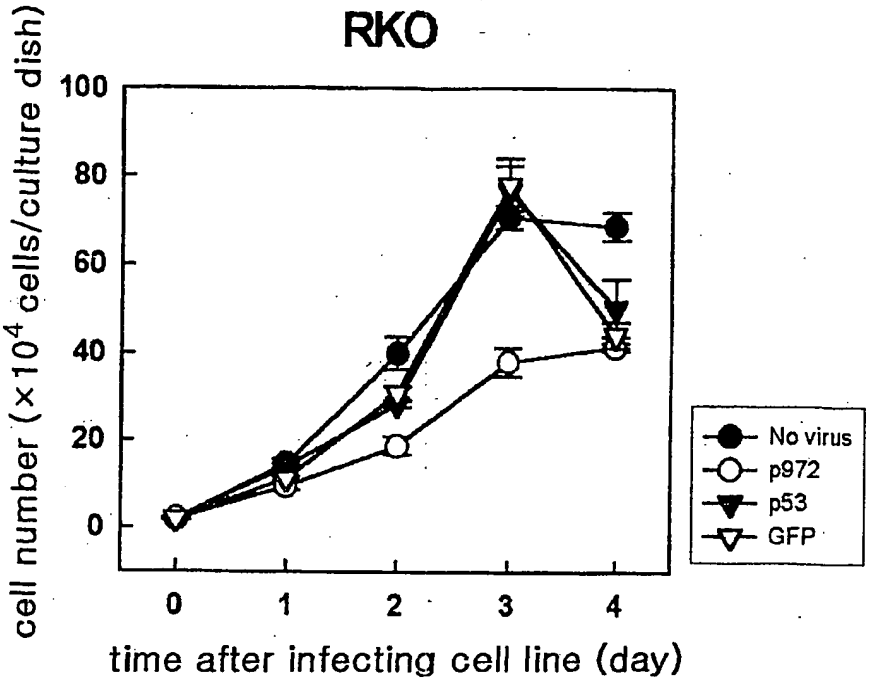
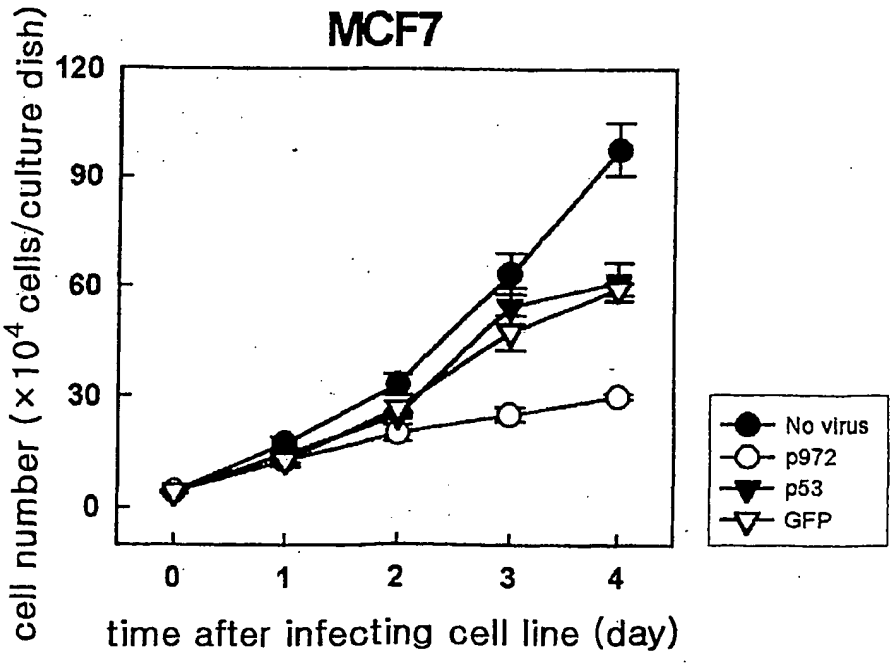

RKO
cell number (×10^4 cells/culture dish)
100
80
60
40
20
0
0
1
2
3
4
time after infecting cell line (day)
No virus
p972
p53
GFP

FIG. 5


MCF7
cell number (×10^4 cells/culture dish)
120
90
60
30
0
0
1
2
3
4
time after infecting cell line (day)
No virus
p972
p53
GFP

112, or that a deposit in accordance with these regulations is or was required. It should be noted, however, that a reference to a biological material, present in an application upon filing, may form the basis for making a deposit, where required, after the filing date of a given application but that the reference to the biological material, itself, cannot be added after filing without risking the prohibited introduction of new matter (35 U.S.C. 132). See the discussion of the Lundak application in MPEP § 2406.01.

2405 Acceptable Depository

37 CFR 1.803. Acceptable depository.

(a) A deposit shall be recognized for the purposes of these regulations if made in

(1) any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or

(2) any other depository recognized to be suitable by the Office. Suitability will be determined by the Commissioner on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes. The Commissioner may seek the advice of impartial consultants on the suitability of a depository. The depository must:

(i) Have a continuous existence;

(ii) Exist independent of the control of the depositor;

(iii) Possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated;

(iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;

(v) Be impartial and objective;

(vi) Furnish samples of the deposited material in an expeditious and proper manner; and

(vii)Promptly notify depositors of its inability to furnish samples, and the reasons why.

(b) A depository seeking status under paragraph (a)(2) of this section must direct a communication to the Commissioner which shall:

(1) Indicate the name and address of the depository to which the communication relates;

(2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (a)(2) of this section, including information on its legal status, scientific standing, staff and facilities;

(3) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;

(4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds;

(5) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

(c) A depository having status under paragraph (a)(2) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material by directing a communication to the Commissioner in accordance with paragraph (b) of this section. If a previous communication under paragraph (b) of this section is of record, items in common with the previous communication may be incorporated by reference.

(d) Once a depository is recognized to be suitable by the Commissioner or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office.

37 CFR 1.803 indicates that a depository will be recognized as acceptable for the purposes of these regulations if it is either an International Depositary Authority (IDA) established under the Budapest Treaty, or if it is a depository recognized as suitable by the Commissioner. After the effective date of these regulations, a deposit of biological material which is made in a depository which is not recognized as acceptable under this regulation will not be considered as satisfying the requirements of 35 U.S.C. 112. See *Ex parte Humphreys*, 24 USPQ2d 1255 (Bd. Pat. App. & Int. 1992). On the other hand, if a deposit is not required to satisfy the requirements of 35 U.S.C. 112, it is permissible to make reference to such a deposit even though it may not be in a depository or made under the conditions which are acceptable under these regulations. As new depositories are recognized as suitable by the Commissioner, their identity will be announced in the *Official Gazette*.

An organization may be recognized as suitable by the Office if the procedure and conditions specified in 37 CFR 1.803(a)(2) and 37 CFR 1.803(b) are followed. Generally, it is not the intention of the Office to recognize as suitable any organization where the need for a suitable depository for patent purposes is being met by depositories recognized as IDAs under the Budapest Treaty. Suitability will be judged by the Commissioner, based on need and the information supplied by the organization seeking status, and information obtained from other sources that may be consulted.

While there is a desire to provide flexibility to a patent applicant in selecting an appropriate depository, these rules are not intended to permit each patent applicant to become its own depository since both the patent owner and the public have an interest in the continued availability and accessibility of the deposit

during the enforceable life of the patent, and the public has a continuing interest in its availability when the patent is no longer enforceable. The concept of a depository independent of the control of the depositor or an IDA as an acceptable depository is based on the need and desire to ensure the safe and reliable storage of a deposited biological material under circumstances that are substantially free of the opportunity for intentional mishandling or negligent handling of the deposited material. The use of an independent depository or internationally recognized depository will tend to preserve the integrity of the deposit process against those that may accidentally alter the deposited material, may wish to tamper with the deposited material or may wish to resume control of its availability when the patent is no longer enforceable, and will tend to preserve the interest of the public in the access to the biological material once the term of the patent expires.

When a depository having status under 37 CFR 1.803(a)(2) seeks to change the kinds of biological materials that it will accept and maintain for the purposes of these rules, a communication requesting such a change should be directed to the Commissioner containing the information requested in 37 CFR 1.803(b). When such a change is requested, the requesting depository should provide a complete list of the kinds of biological materials it will accept.

37 CFR 1.803(d) indicates that once a depository is recognized as suitable for the purposes of this rule, or has defaulted or discontinued its performance under this section, notice thereof will be published in the *Official Gazette* of the Patent and Trademark Office. A current list (as of January, 1998) of IDAs recognized under the Budapest Treaty, with addresses, is included below. The mere fact that a deposit has been made in one of these depositories does not mean that the terms of the deposit meet either the requirements of the Budapest Treaty or the deposit regulations. Many of the depositories recognized under the Budapest Treaty have many different arrangements under which biological material may be stored.

The World Intellectual Property Organization (WIPO) publishes a Guide to the Deposit of Microorganisms under the Budapest Treaty (WIPO Publication No. 661 (E)) on the procedures and requirements concerning the deposit of biological material, including procedures for obtaining a sample of deposited material, in each of the international depository authorities.

CURRENT IDAs

The following constitutes the list of IDAs recognized under the Budapest Treaty. The list is current as of July, 2001.

Advanced Biotechnology Center (ABC)
Interlab Cell Line Collection
(Biotechnology Dept.)
Largo Rossana Benzi, 10
16132 Genova
Italy

Agricultural Research Service
Culture Collection (NRRL)
1815 North University Street
Peoria, Illinois 61604
USA

American Type Culture Collection (ATCC)
10801 University Blvd.
Manassas, Virginia 20110-2209
USA

Australian Government Analytical
Laboratories (AGAL)
The New South Wales Regional Laboratory
1, Suakin Street
Pymble, NSW 2073
Australia

Belgian Coordinated Collections of
Microorganisms (BCCM)
Prime Minister's Services
Federal Office for Scientific, Technical and
Cultural Affairs (OSTC)
Rue de la Science 8
B-1000 Brussells
Belgium

Bureau of Microbiology at Health Canada (BMHC)
Federal Laboratories for Health Canada
Room H5190
1015 Arlington Street
Winnipeg, Manitoba
Canada R3E 3R2

Centraalbureau voor Schimmelcultures (CBS)

Oosterstraat 1
Postbus 273
NL-3740 AG Baarn
Netherlands

China Center for Type Culture Collection (CCTCC)
Wuhan University
Wuhan 430072
China

China General Microbiological Culture Center (CGMCC)
China Committee for Culture Collection of Microorganisms
P.O. Box 2714
Beijing 100080
China

Colección Española de Cultivos Tipo (CECT)
Universidad de Valencia
Edificio de Investigación
Campus de Burjasot
46100 Burjasot (Valencia)
Spain

Collection Nationale De Cultures De Micro-organismes (CNCM)
Institut Pasteur
28, rue du Dr Roux
75724 Paris Cédex 15
France

Collection of Industrial Yeasts DBVPG
Applied Microbiology Section
Department of Plant Biology
Faculty of Agriculture
University of Perugia
Borgo 20 Giugno, 74
06122 Perugia
Italy

Culture Collection of Algae and Protozoa (CCAP)
Institute of Freshwater Ecology
Windermere Laboratory
Ambleside, Cumbria LA22 0LP
United Kingdom and Dunstaffnage Marine Laboratory
P.O. Box 3
Oban, Argyll PA34 4AD
United Kingdom

Culture Collection of Yeasts (CCY)
Institute of Chemistry
Slovak Academy of Sciences
Dúbravská cesta 9
842 38 Bratislava,
Slovakia

Czech Collection of Microorganisms (CCM)
Masaryc University
ul. Tvrdého 14
602 00 Brno
Czech Republic

DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)
Mascheroder Weg 1b
D-38124 Braunschweig
Germany

European Collection of Cell Cultures (ECACC)
Vaccine Research and Production Laboratory
Public Health Laboratory Service
Centre for Applied Microbiology and Research
Porton Down
Salisbury, Wiltshire SP4 0JG
United Kingdom

Institute of Agriculture and Food Biotechnology (IAFB)
Collection of Industrial Microorganisms
Ul. Rakowiecka 36
02-532 Warsaw, Poland

International Mycological Institute (IMI)
Bakeham Lane
Englefield Green
Egham, Surrey TW20 9TY
United Kingdom

International Patent Organism Depositary (IPOD)
AIST Tsukuba Central 6
1-1, Higashi 1-chome
Tsukuba-shi, Ibaraki-Ken 305-8566
Japan

Korean Cell Line Research Foundation (KCLRF)
Cancer Research Institute
Seoul National University College of Medicine
28 Yungon-dong, Chongno-gu
Seoul 110-799
Republic of Korea

Korean Collection for Type Cultures (KCTC)
52, Oun-dong,
Yusong-Ku
Taejon 305-333
Republic of Korea

Korean Culture Center of Microorganisms (KCCM)
College of Engineering
Yonsei University
Sodaemun gu
Seoul 120-749
Republic of Korea

Microbial Strain Collection of Latvia (MSCL)
University of Latvia
Faculty of Biology
Blvd. Kronvalda 4
LV-1586 Riga
Latvia

National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)
125, Tsarigradskochausse Blvd.
Block 2
1113 Sofia
Bulgaria

National Collection of Agricultural and Industrial Microorganisms (NCAIM)
Department of Microbiology and Biotechnology
University of Horticulture and the Food Industry
Somlói út 14-16
H-1118 Budapest
Hungary

National Collection of Type Cultures (NCTC)
Central Public Health Laboratory
61 Colindale Avenue
London, NW9 5HT
United Kingdom

National Collection of Yeast Cultures (NCYC)
AFRC Institute of Food Research
Norwich Laboratory
Colney Lane
Norwich NR4 7UA
United Kingdom

National Collections of Industrial, Food and Marine Bacteria (NCIMB)
23 St. Machar Drive
Aberdeen AB2 1RY
Scotland, United Kingdom

National Research Center of Antibiotics
Nagatinskaya Street 3-a
Moscow 113105
Russian Federation

Polish Collection of Microorganisms (PCM)
Institute of Immunology and Experimental Therapy
Polish Academy of Sciences
Ul. Weigla 12
53-114 Wroclaw
Poland

Russian Collection of Microorganisms (VKM)
Prospekt Naouki, 5
142292 Puschino (Moscow Region)
Russian Federation

Russian National Collection of Industrial Microorganisms (VKPM)
GNII Genetika
Dorozhny proezd. 1
Moscow 113545
Russian Federation

2406 Time of Making an Original Deposit

37 CFR 1.804. Time of making an original deposit.

(a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for patent or, subject to § 1.809, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.

37 CFR 1.804 specifies the time for making an original deposit to fulfill the requirements of 35 U.S.C. 112. For the reasons discussed throughout this section, it is recommended that a deposit be made before the filing date of the application. However, for the purposes of complying with the requirements of 35 U.S.C. 112, a deposit of a biological material may be made at any time before filing the application for patent or during the pendency of the application